



Design of Ketoconazole Soap Strips

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Abstract

Fungal infections like tinea, cutaneous candidiasis and seborrhoeic dermatitis is always a worry and uneasiness to the suffering patients; hence the drug selected in the present study is Ketoconazole which has broad spectrum antifungal activity and belongs to azole class. The preparation and study of medicated paper soap strips was carried out experiments in two phases. Phase-I Studies optimization, which is done for water absorption capacity of paper by determining the parameters like, weight gain, thickness, size & shape, foam test and stability studies. From these parameters best soap, concentration of liquid soap solution and paper is screened out. Phase-II Studies involves incorporation of drug in the best liquid soap solution and paper which were chosen from Phase-I Studies. The incorporation of drug in medicated paper soap strip was achieved by Emulsification technique and application of soap solution over paper was achieved by dipping technique and characterized for thickness, weight, foam test, stability studies, drug content uniformity, FTIR, in vitro drug release studies which were carried out in 0.1N HCl media using prehydrated cellophane membrane for 30 mins. The result indicated that 39.39% drug release in 30 mins. The primary skin irritation studies carried out on guinea pigs, showed no sensitization and edema on skin after 72 hours of application. The microbial studies indicated the drug action through zone of inhibition. The results of present study revealed that the prepared medicated paper soap strips of Ketoconazole is economic, convenient, gives good foam on application, uniform drug content and no skin irritation on animals.

Keywords: Ketoconazole, soap strips and foam.

INTRODUCTION:

Presence of thick foam on the infected part causes hydration of stratum corneum for better permeation of drug.^{1,2,3,4,5} Fungal infections are contagious, spread from person to person. Close contact or sharing a comb or hairbrush with someone who has tinea can spread the fungus from one person to another. Because fungi need a warm, dark, and humid place to grow, public showers, pools, locker rooms, and even the warmth of shoes and socks can give fungi the perfect opportunity to strike. They can be controlled in their initial stage by proper medications. For this purpose there are many topical drug delivery systems available including medicated soap bars and shampoos etc. Their disadvantages being their economy, wastage, recurrence on reuse, no accurate dosage, formation of foam etc. hence the present work is designed to formulate and evaluate medicated soap strips to counter all the above disadvantages.

MATERIALS AND METHODS:

Drug Ketoconazole was a gift sample from Torrent Pvt. Ltd. Ahmedabad. Sabouraud's dextrose agar was a gift sample from Himedia Laboratories Ltd., Mumbai. Soap Bar-A Soap Bar-B Soap Bar-C were purchase from Local Market. Whattman filter paper No. 1, 40, 41 & 42 was a gift sample from Venkatesh Chemicals, Gulbarga. Butter Paper and Bond Paper (Royal Executive Bond) were purchase from Local Market. HCL was purchased from Qualigen Fine Chemicals, Mumbai.

Preparation of formulation:

Phase-I Studies: Optimization Experiments

Selection of Soap Solution: Three non-medicated soaps of different brands were selected and coded as MB-A, MB-B and MB-C and liquid soap solution of varied concentrations (5, 10, 15% w/v) were prepared. During the preparation of Liquid soap solutions formation of bubbles and lumps was avoided. The criteria to select a good soap were foam test.

Selection of paper: Nine different branded papers selected in the present study and coded as A, B, C, D, E, F, G, H and I. The criteria for selection of a good paper being their absorption capacity weight and thickness.

Preparation of non-medicated paper Soap Strips: The paper Soap Strips was prepared by “Dipping Technique” using modified disintegration apparatus and air dried for 12 hours at $37\pm 2^\circ\text{C}$.

Characterization of Prepared soap strips: The prepared formulations were subjected for the determination of size and shape, thickness, weight variation, pH and Foam tests by reported standard methods and an average result of 20 strips were taken.

Phase-II Studies:

Formulation of Medicated Paper Soap Strips: The drug is incorporated in the selected formulation which yielded good soap absorption capacity in phase-I studies.

Accurately weighted drug 2% ketoconazole mixed with soap powder and added to distilled water under constant and continuous stirring conditions for 1 hour. Until a uniform liquid soap-drug solution was formed and then the paper soap strips were prepared (Table-1).

Table No. 1
Formula used to prepare Ketoconazole Soap Strips

Sl. No	Ingredient	Quantity Taken
1.	MB-C	15 gms. Each
2.	Ketoconazole	2 gms.
3.	Distilled Water	100 ml.

In-vitro drug release studies under simulated dermatological conditions:^{6,7,8} the drug release from medicated Soap Strips was carried out by stationary dialysis method using prehydrated cellophane membrane as barrier in 0.1N HCl media which was maintained at 37°C temperature for a period of 30 minutes. 10ml. samples were collected from the Receptor compartment and the same ml. of fresh 0.1N HCl was replaced at every 10 minutes time interval for a period of 30 mins. The drug content was estimated by measuring the absorbance at 222.4 nm in a 1700 UV Shimadzu spectrophotometer.

Primary Skin Irritation Test:⁹ 3 healthy guinea pigs of either sex were selected for the study and maintained with normal food and water during the test period of 72 hrs. The hair from the upper portion of waist (lower back portion) was shaved and cleaned with surgical spirit to expose sufficiently large test area. Thick foam, obtained on hydration of a soap strip in 2 ml. of distilled water was applied to the test area of each animal. Animals were under observation for any erythema and / or edema for 72 hours.

Microbiological Studies:^{11, 12, 13} by taking scrapings collected from the diseased patient under the supervision of Dermatologist using the standard cup plate method. The samples were stored in peptone water, before inoculation into sabouraud's dextrose agar media and then incubated at 30°C for 5-7 days. Antifungal activity of prepared formulations were tested against lipophilic yeast *Malassezia furfur* (i.e., *pityrosporum orbiculare* and *pityrosporum ovale*) as the organism is involved with superficial infection such as pityriasis versicolor (*Tinea versicolor*) and 77eborrheic dermatitis.

Stability studies:¹⁴ The stability studies were performed at $37^\circ\text{C} \pm 2^\circ\text{C}$ temperature over a period of six months on the prepared medicated paper soap strips pH the changes physical appearance and drug content was observed.

IR spectral analysis for Drug-excipient interactions:¹⁵ The studies were carried out using IR method with the help of perkin-elmer 1615 spectrophotometer.

RESULTS AND DISCUSSION:

Among the several brands of water absorbable papers studied, the paper coded F was found to have optimum absorption capacity of soap with 0.23mm Thickness (Fig.No.1) & 0.31gm weight (Fig.No.2). Among the different brands of soaps in their varied concentrations studied; the formulation code F of 15% w/v liquid soap solution of soap MB-C yielded

satisfactory foam test of 20ml foam height (Fig.No.3). All the Soap Strips have pH range of 7.00 to 7.2. The prepared 2% Ketoconazole formulations found to have uniform drug content 99.05%, weight of 0.50 gm. And 0.25mm of thickness. The medicated soap strips found to give optimum foam height of 47 ml. (Table No.-2) In-vitro drug release revealed that at the end of 30 mins. The % amount of drug released from 2% Ketoconazole paper Soap Strips was 39.68%. (Table-3). Primary Skin Irritation Test showed none of the prepared medicated paper Soap Strips showed any kind of erythema and / or edema, 24 hrs. 48 hrs. & 72 hrs. of application, indicating that the prepared formulations were non-irritant on the skin of guinea pig. Microbiological Studies showed good zone of inhibition i.e., 1.16 cm. of diameter. Stability studies results revealed no change in pH and physical appearance and drug content in the formulations. **IR spectral analysis for Drug-excipient interactions:** the undisturbed peaks of pure drug at 1646.37 cm^{-1} which is due to carboxyl group and 1372.06 cm^{-1} and 1174.73 cm^{-1} due to alkyl aryl ethers in the 2% Ketoconazole medicated paper soap strips; conforms that there is no drug excipient interaction in the prepared formulations.

Phase-I Studies:

Histogram showing optimization experimental results of ketoconazole soap strips prepared from soap solution (15% w/v)

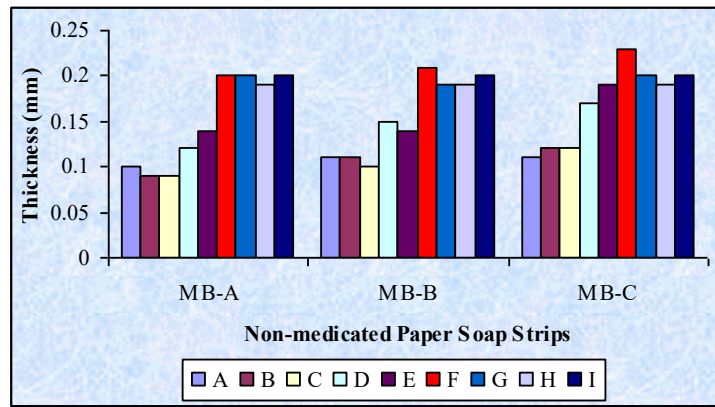


Fig. No.1: Thickness (mm)

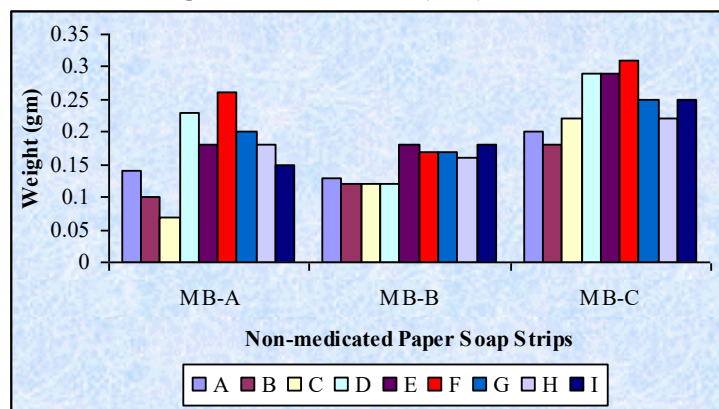


Fig. No. 2: Weight (gm)

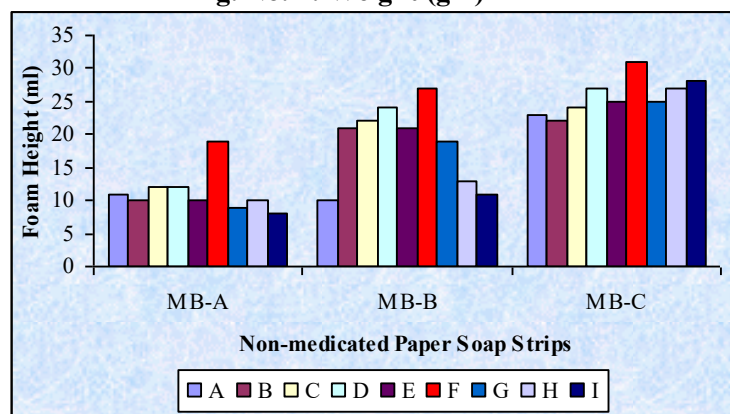


Fig. No. 3: Foam Height (ml.)

Table No. 2
Physico-chemical Parameters of prepared Ketoconazole soap strips

Sl. No.	Parameters	2% Ketoconazole soap strips
1.	Thickness (mm)	0.24±0.02
2.	Weight variation (gm)	0.50±0.01
3.	Foam height (ml)	48±0.00
4.	Drug content (mg)	98.05%
5.	PH	7.1

Table No. 3
In-vitro drug release profile of 2% Ketoconazole Soap Strips

Sl. No.	Time (mins)	Square root of time (mins)	Cumulative percent drug released	Cumulative percent drug retained	Log Cumulative percent drug retained
1.	0	0.000	0.00	0.00	0.000
2.	5	2.236	14.44	85.57	1.838
3.	10	3.162	21.01	79.00	1.806
4.	15	3.872	25.38	74.63	1.977
5.	20	4.472	29.13	70.88	1.955
6.	25	5.000	37.67	62.34	1.902
7.	30	5.477	41.05	69.00	1.879

* Each reading is a mean of three replicates.

Fig 4: Primary Skin Irritation Test of 2% Ketoconazole Soap Strips



Before Application



After 72 hrs. of Application

Fig 5: 2% Ketoconazole Soap Strips**CONCLUSION:**

The results of our study are economical, convenient to use and new design of a dosage form to use for dermatological disorders. The formulations are designed for the use to the patients of all ages, sex.

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